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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/094,293	06/27/2001	Walter E. Roorda	50623.00041 (2742)	5539

30256 7598 03/20/2004

SQUIRE, SANDERS & DEMPSEY L.L.P.  
600 HANSEN WAY  
PALO ALTO, CA 94304-1043

EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT

PAPER NUMBER

1762

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/894,293

Applicant(s)

ROORDA, WOUTER

Examiner

Jennifer K Michener

Art Unit

1762

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5, 9-13, 15-18, 20-22 and 24-44 is/are pending in the application.
- 4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 9-13, 15-18, 20-22, 24-34 and 36-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Specification***

1. The objection to the disclosure has been withdrawn.
2. The new paragraph added to the specification which outlines one of the claimed embodiments is accepted by Examiner.

***Claim Rejections - 35 USC § 112***

3. The rejection of claims 1-2, 5, 8-16, 21-22, 24-26, 28, 30-32, 34, 36, and 41-44 under 35 U.S.C. 112, first paragraph, has been withdrawn.
4. Examiner notes the re-insertion of the word "warm" into the claims. Examiner appreciates Applicant's extensive efforts to overcome the numerous new matter rejections of the previous office action by using the word "warm", as it appears in the originally-filed disclosure. While "warm" was rejected under 112, 2<sup>nd</sup> paragraph in an earlier office action, Examiner does not reapply that rejection, herein. The word "warm" has been interpreted by Examiner to mean that the substrate temperature is greater than the surrounding ambient temperature.

***Claim Rejections - 35 USC § 102***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Pursley (US 6,030,371).

Examiner maintains the rejection.

7. The rejection of claims 1, 2, and 36 under 35 U.S.C. 102(e) as being anticipated by Bouchier et al. (US 6,534,112 B1) has been withdrawn in favor of the new rejections applied below, as necessitated by amendment.

***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. The rejection of claims 2, 24, 36, and 42 under 35 U.S.C. 103(a) as being unpatentable over Berg (US 5,464,650) in view of Pursley (US 6,030,371) has been withdrawn.

10. Claims 5, 9-13, 22, 26-27, 29, 33, 34, 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al. (US 5,558,900).

The rejection of claims 8 and 14 are withdrawn as being canceled by Applicant.

Examiner maintains the rejection of the remaining claims as the elements of claim 8 have been incorporated into claim 5.

In regards to the addition of the "active agent" to claim 5, Fan teaches such agents in col. 2, line 65.

11. Claims 9-10, 15-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Zhong (US 6,156,373).

The rejection of claim 8 is withdrawn as being canceled by Applicant.

Examiner maintains the rejection of the remaining claims.

12. Claim 21, 30, 31, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Pursley.

Examiner maintains the rejection.

13. Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Whitbourne.

Examiner maintains the rejection.

14. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pursley in view of Whitbourne.

Examiner maintains the rejection.

15. Claims 5, 11-13, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ofstead (US 4,977,901).

Examiner maintains the rejection.

The rejection of claim 14 is withdrawn due to its cancellation.

16. Claims 5, 9-13, 17-18, 20, 26-27, 29, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding (US 5,980,972) in view of Rooz (3,882,816) or Finlay (4,865,879).

Examiner maintains the rejection.

The rejection of claims 8 and 14 are withdrawn due to their cancellation.

17. The rejection of claim 24 under 35 U.S.C. 103(a) as being unpatentable over Bouchier et al. (US 6,534,112) has been withdrawn in favor of inclusion within the rejections, old and new, below, as necessitated by amendment.

18. Claims 1, 2, 24, 36, and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouchier et al. (US 6,534,112) in view of Zhong.

Examiner maintains the rejections of claims 41-42.

Examiner now includes the rejection of claims 1, 2, 24, and 36, as necessitated by the amendment adding spraying to these claims.

19. The rejections of claims 5, 17, 18, 20, 21, 43, and 44 under 35 U.S.C. 103(a) as being unpatentable over Bouchier et al. (US 6,534,112) in view of Ding or Fan have been withdrawn in favor of the new rejections applied below, as necessitated by amendment.

The rejection of claim 14 has been withdrawn due to its cancellation.

*As necessitated by amendment, the following new rejections are made:*

20. Claims 1, 2, 24, 36, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouchier in view of Berg.

Bouchier teaches a method of coating a medical device by preheating a process vessel with the medical device therein (col. 6, line 1), then transferring a preheated coating solution to the process vessel (col. 5, line 67). The coating solution contains an active agent (abstract) in solvent (col. 8, line 28) and may contain a resin (col. 4, line 48). The process vessel is held at a constant elevated temperature during coating (col. 4, line 66).

While Bouchier teaches coating a medical device by flooding or immersion, he fails to teach coating by spraying.

Berg teaches coating stents with solutions of polymer either by spraying or immersion (col. 4, lines 24-30). While either method is acceptable, Berg teaches that one of ordinary skill in the art would make the decision based on the viscosity and surface tension of the solution, however that spraying in a fine mist sometimes improves uniformity and control.

Therefore, since Bouchier teaches immersion of a coating solution on a stent and Berg teaches the interchangeability of spraying and immersion, Berg would have reasonably suggested the use of spraying in the method of Bouchier. It would have been obvious to one of ordinary skill in the art to use the teachings of Berg in the method of Bouchier if he wished to increase uniformity and coating control.

Regarding claims 2 and 36, Bouchier teaches coating metallic stents (col. 10, line 41; col. 8, line 23).

Regarding claim 24, please refer to the previous office action rejection under Bouchier alone, as withdrawn above, and applied now herein, necessitated by amendment.

21. Claims 5, 17-18, 20-21, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouchier in view of Berg as applied to claim 1-2, 24, 36, and 41-42 above, and further in view of Ding or Fan.

Bouchier in view of Berg teaches that which is disclosed above. Bouchier also teaches aeration as outlined in the previous office action.

Additionally and alternatively, as outlined in the previous office action, Ding and Fan teach application of warm gases to evaporate solvents from coated medical devices. For the same reasons as applied to the Bouchier in view of Ding or Fan rejection of the previous office action, Examiner applies this Bouchier in view of Berg and further in view of Ding or Fan rejection, herein.



***Response to Arguments***

22. Applicant's arguments have been considered, but they are not persuasive.

Applicant argues that Pursley teaches applying a coating to a catheter liner and that, while a catheter may be a medical device, a catheter liner is not an implantable medical device. At best, it is argued, that the catheter liner is a component of a medical device. Examiner disagrees.

Pursley states that a catheter may comprise a liner over which the layer of polymer material is placed, therefore the liner is an implantable medical device, just as the catheter is. If a catheter is a coated liner, then the liner is an implantable medical device in the same way that a stent is an implantable medical device, even before it is coated. The intended use limitation of the word "implantable" is met in that the liner is capable of being implanted. Furthermore, Examiner cites 4,560,370 merely as another teaching that catheter liners are implanted (col. 2, lines 40-49).

Applicant argues that Pursley fails to teach any embodiments in which the solvenated polymer is applied to the preheated substrate. It is argued that hindsight is used.

Examiner disagrees.

As outlined in the previous office actions, Pursley teaches applying "coating material" to a pre-heated substrate. The coating material is defined as either powder or solvenated polymer.

Additionally, Examiner notes that in one specific embodiment of Pursley, an atomized spray is used to apply the polymer coating material to a preheated substrate (col. 6,

lines 5-15). The provided, non-limiting, example of an atomized spray is of molten polymer in an inert gas stream. The inert gas stream acts as the "fluid" required by Applicant's claims. In the case that Applicant may change the word "fluid" to "solvent" in an effort to remove this rejection, Examiner notes that pre-heating substrates is known in the art and cites the following to teach the same: 6,358,567 teaches pre-heating substrates to be coated with a solution to decrease evaporation time and to prevent cracks from forming in the final coating and 3,995,075 teaches coating polymer solutions onto pre-heated metal substrates to decrease evaporation time. As solvenated polymers and fluid-based polymers are taught by Pursley, the use of hindsight was unnecessary by Examiner.

Regarding the Fan and Bouchier references, Applicant argues that there is no reasonable expectation of equivalency of spraying and immersion and cites Berg to teach that spraying is often superior to dipping. Examiner disagrees.

Examiner's arguments were directed to the expectation of success and the interchangeability of spraying and immersion. It is well-known in the art that spraying and immersion are often used interchangeably and Examiner cited the Fan reference, alone, making such an assertion. Secondly, in order to provide Applicant with a secondary reference to prove the same, Zhong and Berg were also cited. Zhong teaches equivalence, whereas Berg teaches that selection would be obvious to one of ordinary skill in the art depending on viscosity and surface tension. Examiner maintains

that it would have been obvious to one of ordinary skill in the art to recognize the interchangeability of spraying for immersion based on the qualities of the coating solution. Additionally, as pointed out by Applicant, Berg teaches that spraying *sometimes* provides superior results when compared to immersion. This further enhances Examiner's argument that one of ordinary skill in the art would have been motivated by references such as Berg, to interchange spraying for immersion with the expectation of successful results since, in some circumstances, spraying is taught to improve the coating quality. If, as Applicant contends, one of ordinary skill in the art is aware that spraying and immersion are sometimes taught to be equivalent and sometimes taught to both be acceptable, with spraying being superior, then one of ordinary skill in the art would have been motivated to use spraying for equivalent or superior results.

Applicant argues, with regard to Ofstead that Examiner has not identified a benefit of skipping a step to sacrifice coating quality and that if such a step were skipped, as is done by Applicant, that Applicant's production of acceptable coatings is unexpected. Examiner disagrees.

Time savings is a significant benefit of skipping or abbreviating a drying step. A decrease in production time would yield greater profits. And, based on the teachings of Ofstead, elimination of the step may indeed produce inferior results, however there is a range of "acceptable" results in industry. The loss of some degree of quality for a large savings in time is a decision that one of ordinary skill in the art would be capable of

making. Additionally, the fact that Ofstead teaches that the absence of air-drying creates the inferior results is a teaching that the method has already been performed by another Applicant and that, while inferior, does produce a coated product which may be acceptable to an ordinary artisan reading the teachings of Ofstead.

Applicant argues that Ding's separate solutions do not meet Applicant's limitation of a combined active agent and polymer.

Examiner disagrees.

Ding teaches the application of the solutions sequentially or simultaneously (abstract). When applied simultaneously, the elements of the solution intermingle and are applied together. Additionally, Ding teaches that the polymer system may contain small amounts of drug and vice versa (col. 1, lines 50-55), meeting the claim as amended.

### ***Conclusion***

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goicoechea is cited for teaching applying coating to a rotating stent on a mandrel and then blowing hot air on the stent to decrease evaporation time (col. 4, lines 50-55).

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Michener whose telephone number is 571-272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications. Any inquiry of a general nature or relating to the status of this

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application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener  
February 5, 2004



SHRIVE P. BECK  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700